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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/785,455 01/17/97 HODGSON

J P31353

EXAMINER

HM11/0608

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY UW2220
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HOBBS, L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/08/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2/2/98

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-55 is/are pending in the application.
Of the above, claim(s) 13-25, 27 is/are withdrawn from consideration.
☒ Claim(s) 28-43, 45-55 is/are allowed.
☒ Claim(s) 1-3, 7-12, 26, 44 is/are rejected.
☒ Claim(s) 4-6 is/are objected to.
☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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DETAILED ACTION

1. This application has been filed with informal drawings which are acceptable for examination purposes only, please refer to the substitute PTO-948 form attached to Paper No. 6, mailed October 26, 1997, for details. The formal drawings for this application were submitted as Paper No. 8, received February 17, 1998, and will be forwarded to the Draftsperson for review.

2. Acknowledgment is made of applicant's claim for priority based on two applications filed in the United Kingdom: 9601095.4, filed January 19, 1996, and 9615845.6, filed January 27, 1996. The priority applications were submitted as Paper No. 7, received October 20, 1997.

3. Claims 1-55 are pending in this application; claims 1-12, 26 and 28-55 are under examination. Claims 13-25 and 27 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

4. The rejection of claim 26 is rejected under 35 U.S.C. § 112, first paragraph is withdrawn in view of the amendment to the claim.

5. The rejection of claim 26 is rejected under 35 U.S.C. § 112, second paragraph si

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withdrawn in view of the amendment to the claim.

6. The rejection of claims 1, 2, 7 and 8 under 35 U.S.C. 102(a) is withdrawn in view of the amendments to the claims.

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7. The rejection of claims 1-3 and 7-12 under 35 U.S.C. 103(a) is withdrawn in view of the amendments to the claims.

8. The rejection of claim 1, with depending claims 2, 3, 8-12, and claim 7 under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the sequences and useful fragments thereof, and their complements, as disclosed in the specification, not to any sequence with 70% or more homology to the disclosed sequences (claims 1 and 7) is maintained. See M.P.E.P. §§ 706.03(n) and 706.03(z). The claims are broader than the enablement provided by the disclosure with regard to the extremely large number of DNA fragments, some encoding binding and/or enzymatic activity, naturally occurring or synthetic, encompassed.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands, 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4)

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the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

These claims are drawn to encompass DNA fragments which encode any protein having 70% identity to the sequences disclosed in the specification. The specification, however, only discloses Seq. ID Nos.: 1 and 2. Despite knowledge in the art for the production of nucleotide sequences encoding peptide fragments, the specification fails to provide guidance regarding how to make and use all of the possible fragments or structures with 70%, or more, homology, only some of which would retain a stated activity.

The amino acid sequence of a protein determines its structural and functional properties, and predictability of which amino acids can be changed or removed from a protein's sequence and still result in similar activity is extremely complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's structure from mere sequence data are limited. Since detailed information regarding the structural and functional requirements of this protein is lacking, it is unpredictable as to which peptide fragments, if any, meet the limitations of the claims. Therefore, one of ordinary skill would require guidance, such as information regarding the extent of peptide fragmentation, the location of fragmentation sites, and the specific amino acid changes which would result in the preservation of the stated activity, and

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be 70%, or more, homologous, in order to make and use DNA fragments, portions and sequences with 70%, or more, homology in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

5 Applicants argue that the specification includes teachings of coding polynucleotides, which are useful for generating active polypeptides, and non-coding polynucleotides, which are useful for other assays and diagnostic screens, therefore this rejection is improper. Applicants' arguments have been fully considered but are not deemed persuasive. While it is true that the specification, as quoted extensively in the
10 response, teaches possible uses for coding as well as non-coding polynucleotides, it does not describe any structural information regarding this polynucleotide, by examples of the instant polynucleotide, or by guidance in the prior art for other similar *Staphylococcal* MetRS polynucleotides, which would give guidance to one of skill in the art regarding how to use the broadly claimed range of polynucleotides.

15 The specification does not disclose which 30% of the nucleotides comprised within the multiple sequences which encode Seq. ID No.: 2, or the mature polypeptide encoded by the deposited gene, could be changed and still maintain the ability of the sequences to encode an active protein. The specification also does not disclose which 30% of the nucleotides comprised within the multiple sequences which encode Seq. ID
20 No.: 2, or the mature polypeptide encoded by the deposited gene, could be altered and

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retain the usefulness of the sequences for the various assays, diagnostic probes and research reagents disclosed as possible uses for a non-coding polynucleotide.

9. The objection to claims 4-6 as being dependent upon a rejected base claim is maintained. However, these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 12 and 44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the limitation "fragments". There is insufficient antecedent basis for such a limitation as the independent claims from which these claims depend do not recite "fragments" of the gene encoding MetRS.

11. Claim 26 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant intends to claim with the recitation of Seq. ID No.: 1 on line 3. Seq. ID No.: 1 refers to a DNA sequence, not an amino acid sequence. For the purposes of compact prosecution, the examiner has interpreted this to mean Seq. ID No.: 2.

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12. Claims 1-12, 26 and 28-53 are allowable over the prior art of record.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).


A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

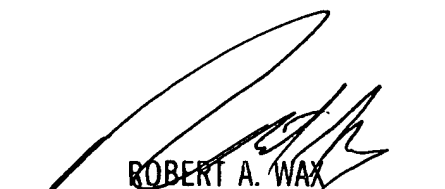
14. Any inquiry concerning this communication or earlier communications should be directed to Lisa J. Hobbs whose telephone number is (703) 308-6573.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission to the attention of the examiner in Art Unit 1652. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (October 19, 1988) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The FAX telephone number is (703) 308-4242. Note: If applicants do submit a paper by facsimile, the original signed copy should be retained by applicants or applicants' representative. No duplicate copies should be submitted so as to avoid the processing of duplicate papers in the Office.


Lisa J. Hobbs, Ph.D.
Patent Examiner
Art Unit 1652


ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180-1450

June 8, 1998